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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,115	01/07/2004	Timothy D. Hey	DAS-104XC1	8974
23557 7590 08/24/2007 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			EXAMINER KOSSON, ROSANNE	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 08/24/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/754,115

Applicant(s)

HEY ET AL.

Examiner

Rosanne Kosson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-25 and 34-42 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-25, 34, 35 and 38-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 21-25, 34, 35 and 38-42, all in part, and 36-37

**DETAILED ACTION*****Election/Restrictions***

The amendment filed on August 6, 2007 has been received and entered. Claims 21, 34, 36 and 38 have been amended. No claims have been canceled or added. As discussed numerous times with Applicants, in responses, telephone interviews and an in-person interview, the claims are examined to the extent that they read on the elected invention, a composition comprising three proteins, SEQ ID NO:34 as the Xenorhabdus A protein, a B protein from Photorhabdus and a C protein from Photorhabdus. The claims in the most recent claim set have been broadened to include claims to many inventions, including claims to many protein sequences, which include many non-elected protein sequences. Claims 21-25, 34, 35 and 38-42 are examined to the extent that they read on the elected invention. To the extent that they do not read on the elected invention, they are withdrawn. The portions of claims 21, 34 and 38 that are examined herewith are those in which A is SEQ ID NO:34, B is SEQ ID NO:22 or 45 or 56- a Photorhabdus protein- and C is SEQ ID NO:25 or 47 or 57- a Photorhabdus protein. The portions of these claims that recite other sequences (SEQ ID NOS:14, 18, 49, 16 and 51 and the "wherein" clauses) are withdrawn. Claims 36-37 do not read on the elected invention at all and are withdrawn.

In reply to Applicants' comment that their claim language was confusing and misunderstood because "when" was interpreted to mean "only when," Applicants comment is confusing. The claim language was not confusing and the meaning of "when" was not confusing. But, if the word "only" had been used, the claims would have had no clear meaning at all. The claims simply did not read on the elected invention, and, if a "wherein" clause is present, the claims cannot be interpreted as though the "wherein" clause were absent or both

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present and absent. The restriction requirement has proven to be a significant difficulty in this application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112, first paragraph***

Upon reconsideration, the written description rejections in the previous Office action are withdrawn.

Claims 21-25 are again rejected and claims 34, 40 and 41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of controlling or inhibiting an insect by contacting the insect with a composition comprising SEQ ID NO: 34, plus one of SEQ ID NOS:22, 45 or 56, plus one of SEQ ID NOS:25, 47 or 57, does not reasonably provide enablement for a method of controlling or inhibiting an insect by contacting the insect with a composition comprising any variant having 95% sequence identity to any or all of the aforementioned proteins. The specification also does not provide enablement for a method of controlling or inhibiting an insect by contacting the insect with a composition comprising proteins encoded by polynucleotides that hybridize under stringent conditions (medium stringency conditions) to any or all of the aforementioned proteins. Consequently, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. With respect to sequences having a particular % sequence identity to the elected protein sequences, this rejection was discussed in the previous Office actions with respect to claims 1, 2, 4, 5, 12, 14, 32 and 33.

As discussed in the previous Office action, Applicants have not responded specifically to the enablement rejection. They stated merely that their response to the written description

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rejection also addresses the enablement rejection. But, the response to the written description rejection does not address the enablement rejection. Applicants have claimed several very large genera of proteins and polynucleotides encoding these proteins (variants of the elected protein sequences and sequences that hybridize under medium-stringency conditions to polynucleotides encoding the elected protein sequences), but have not disclosed any species of these genera. Because Applicants have not disclosed any species of these claimed genera, and because Applicants have not provided any systematic procedure for identifying these undisclosed species, it cannot be predicted that such species exist. Additionally, it would be undue experimentation to come up with the systematic guidance needed to identify and test these species. In view of the foregoing, the rejection of record is maintained.

Additionally, toward advancing prosecution, it has been discussed several times that, because there is no correlation between structure and function in the many *Xenorhabdus* and *Photorhabdus* proteins disclosed in the specification, as highlighted by Applicants in the in-person interview, retaining the "hybridization under stringent conditions" language and the % sequence identity language in the claims does not provide for patentable claims. For this reason, Applicants were advised that they could recite a set of specifically named *Photorhabdus* B proteins and a set of specifically named *Photorhabdus* C proteins in the claims. Applicants are encouraged to amend the claims accordingly.

***Claim Rejections - 35 USC § 112, second paragraph***

In view of Applicants' amendments to the claims, these rejections are withdrawn.

***Double Patenting- Obviousness-Type***

Claims 21-25 are again provisionally rejected, and claims 34, 35 and 38-42 are

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provisionally rejected, on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26, 28 and 29 of copending Application No. 11/070,573. This rejection was discussed in the previous Office action. To reiterate, although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a method of controlling or inhibiting an insect, comprising contacting the insect with a composition comprising Proteins A, B and C (SEQ ID NOS:34, 45 (or 22 or 56) and 47 (or 25 or 57), respectively), while the copending claims recite a method of preventing an insect from feeding on a plant, a more specific form of inhibition, comprising contacting the insect with a composition comprising Proteins A, B and C (SEQ ID NOS:23, 6 (or 5 or 7) and 14 (or 12 or 16), respectively, which are the same sequences as instant SEQ ID NOS:34, 45 (or 22 or 56) and 47 (or 25 or 57)). In the copending application, Proteins B and C are part of a fusion protein, while, in the instant application, Proteins B and C may or may not be linked in a fusion protein, but the copending claims are a narrower version of the instant claims. These two claim sets would not have been restricted apart had they been presented together in one application.

Applicants have not responded to this rejection. Therefore, the rejection of record is still outstanding and is maintained.

No claim is allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after


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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson   
Examiner, Art Unit 1652

rk/2007-08-17

/Rebecca Prouty/  
Primary Examiner  
Art Unit 1652